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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/521,454   | 11/29/2005  | Ichiro Hirao         | 0230-0222PUS1                   | 8799                        |
| 2292 7590 10/03/2007<br>BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER<br>EPPS FORD, JANET L  |                             |
|  |             |                      | ART UNIT<br>1633                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>10/03/2007 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

Application No.

10/521,454

Applicant(s)

HIRAO ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claims 4-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-10 have not been further treated on the merits. Claim 3 recites dependency on claim 1 or 2. Claim 4 recites dependency on claims 1 to 3, however claim 3 is a multiple dependent claim. Claims 5-10 recites dependency on claims 1 to 4, however claims 3-4 are multiple dependent claims.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ohtsuki et al.  
Claim 1 recites a nucleoside or nucleotide having a 5-substituted-2-oxo(1H)-pyridin-3-yl group as a base.

Ohtsuki et al. discloses the following unnatural nucleobase (see m<sup>5</sup>y base):

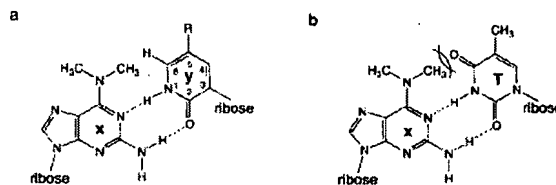


Fig. 1. The unnatural x-y (y: R = H, m<sup>5</sup>y: R = CH<sub>3</sub>) pair (a) in comparison with a noncognate x-T pair (b).

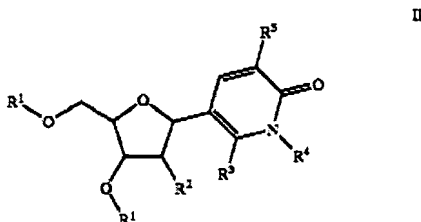
**Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehler et al. (US Patent NO. 6447998 or 6495672 or US application number 20030120065).

6. Froehler et al. discloses 2-aminopyridine and 2-pyridone C-nucleosides and oligonucleotides containing the subject nucleosides. The nucleosides are useful in the preparation of the subject oligonucleotides. The oligonucleotides are useful in oligonucleotide-based diagnosis and separation through triplex binding. In one embodiment these modified nucleobases comprise the following structure (see col. 2):



wherein:

each  $R^1$  is independently H or a hydroxy protecting group,  
or both  $R^1$  groups are taken together to form a cyclic  
hydroxy protecting group;

$R^2$  is H, F,  $-OR^1$ , or  $-OR^4$ ;

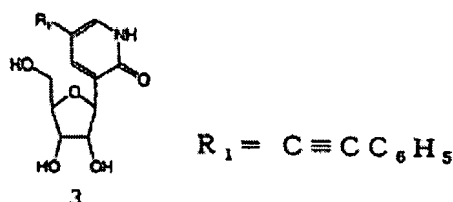
$R^3$  is H or  $-CH_3$ ;

each  $R^4$  of formula I and II is independently H or an amine  
protecting group, or both  $R^4$  groups of formula I are  
taken together to form a cyclic amine protecting group;

$R^5$  is H,  $-CH_3$ , or  $-C\equiv C-CH_3$ ; and

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An exemplary compound according to the present invention comprises the following structure, see Figure 3:



The instantly claimed nucleosides or nucleotides comprise a structure that differs from the prior art to the extent that the positions at which the ribose and the alkynyl groups attach to the pyridine ring are different.

It would have been obvious to the ordinary skilled art seeking alternative nucleobases to vary the positions of the substituents in the pyridine ring to produce another nucleobase to be used for the same purpose, namely for incorporation into nucleic acid molecules. One of ordinary skill in the art would have been motivated to modify the teachings of Froehler et al. to design the molecules of the instant invention, because the claimed compounds are homologous to the compounds of Froehler et al., moreover the compounds of Froehler et al. are disclosed in the art as being useful for the same purpose as the instantly claimed compounds. Moreover, the differences between the prior art compounds and the compounds of Froehler et al. can be characterized as a matter of obvious design choice since the suitability of compounds comprising substituted pyridine nucleobases for incorporation into nucleic acids was previously disclosed in Froehler et al. *In re Leshin*, 125 USPQ 416. Additionally, see MPEP § 2144.09 which states:

**2144.09 Close Structural Similarity Between Chemical Compounds (Homologs, Analogues, Isomers)**

**REJECTION BASED ON CLOSE STRUCTURAL SIMILARITY IS FOUNDED ON THE EXPECTATION THAT COMPOUNDS SIMILAR IN STRUCTURE WILL HAVE SIMILAR PROPERTIES**

A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed below and in **MPEP § 2144**) for an extensive review of the case law pertaining to obviousness based on close structural similarity of chemical compounds. See also **MPEP § 2144.08**, paragraph II.A.4.(c).

**HOMOLOGY AND ISOMERISM ARE FACTS WHICH MUST BE CONSIDERED WITH ALL OTHER RELEVANT FACTS IN DETERMINING OBVIOUSNESS**

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious).

Therefore, the invention as a whole would have been *prima facie* obvious over the teachings of Froehler et al.

***Information Disclosure Statement***

7. The information disclosure statement filed 1-14-2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other

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information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner  
Art Unit 1633

JLE